

Remarks

Claims 1-10 and 13-27 are pending. Claim 5 has been withdrawn under an election requirement. Claims 11-12 are cancelled. New claims 21-27 are presented for consideration. No new matter has been added by the amendments. All claim stand rejected. For the reasons set forth below, the grounds of rejection are respectfully traversed.

Claim Rejections – 35 USC § 103

Claims 1-4, 6-10 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer (U.S. Patent No. 4,549,319) in view of Mackwood Ling et al. (U.S. Patent No. 6,241,772). Applicant traverses on grounds that a *prima facie* case of obviousness has not been established. There is no suggestion or motivation to combine the centralizer plug of Mackwood Ling with a compactor instrument, and the record is clear that it was applicant who identified the shortcomings of the prior art and taught the solution.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim elements. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991).

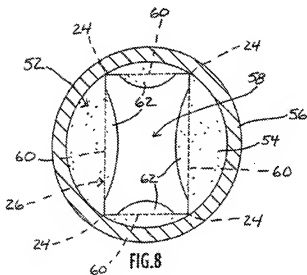
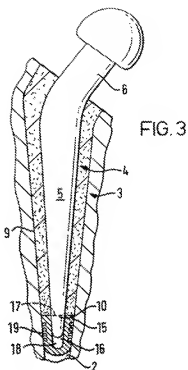
It is respectfully submitted that there is no motivation to combine the cited references as contemplated in the rejection. The Examiner takes the position that Meyer discloses the claimed invention with the exception of the bullet-shaped distal tip comprising three or four fins, spaced at 90 degree spaced locations about the central longitudinal axis, extending radial to the central longitudinal axis and extending longitudinally, distally from the forward end of the body to converge at an apex aligned with the central longitudinal axis, the fins being disposed inwardly. The Examiner interprets Mackwood Ling as disclosing, with reference to Figure 4, a centralizing device for the stem of a prosthesis, including a bullet-shaped distal tip having the foregoing characteristics. The Examiner concludes that it would have been obvious to one of ordinary skill

in the art at the time of the invention to construct the device of Meyer with a bullet-shaped distal tip having the characteristics of Mackwood Ling's centralizer plug, the fins being disposed inwardly in order to centralize the device at the distal end.

The Examiner points to no suggestion, teaching or motivation in the cited references, or in the knowledge generally available to one of ordinary skill in the art at the time of the invention, to provide Meyer's femoral broach with a plurality of fins for use in centralizing the instrument. In addition to the lack of a suggestion or teaching to combine the cited references, there is no motivation to do so because the instrument of Mackwood Ling is used in a very different situation, and to solve a very different problem, than the instrument of applicant or Meyer. Mackwood Ling's centralizer plug is used to position a *cemented* femoral stem in a *previously prepared* femoral canal, while applicant's compactor instrument is used to *prepare* a femoral canal for later receipt of a *cementless* femoral stem. When using a cementless stem, there is no use for a centralizer plug of the type described in Mackwood Ling, because the surgeon prepares the femoral canal to closely receive the cementless stem in a fixed relationship. The close fit serves to position the cementless stem. The significant differences between the structures, functions and uses of cemented and cementless femoral prosthetic stems obviate any motivation to combine.

The Meyer patent, which was filed in 1982, was an early effort to improve the design of cementless stems. Meyer noted that in the early 1980's "orthopedic surgeons most commonly use[d] polymethyl methacrylate (PMMA) cement for fixing artificial joint components to bone." (Meyer, Col. 1, Lines 8-11). Meyer further noted that "[f]ailure of [cemented] prosthetic joint implants is often traceable to failure in the cement fixation." (Meyer, Col. 1, Lines 30-31). Today, cementless stems are used much more commonly than cemented stems, primarily because cementless stems preserve bone stock, are easier to remove than cemented stems, and are less prone to failure. In most cases, a surgeon will initially implant a cementless femoral stem. However, over a period of time (e.g. 20 years), bone loss in the area around an original, or "primary," cementless stem may make it necessary to "revise" the implant by removing the primary stem and replacing it with a "revision" femoral stem. If bone loss is significant, the surgeon will replace the primary cementless stem with a cemented stem.

As shown in Figure 3 of Mackwood Ling at right, cemented stems are configured to fit within a cement mantle 4. The Mackwood Ling centralizer plug 15 has an annular opening 10 that is configured to receive a distal end of a cemented stem 6 having an annular cross-section and a smooth surface. The centralizer plug 15 plugs the previously prepared intramedullary canal, and also assists in centering the stem 6 in the canal during the steps of pouring and curing the cement mantle 4 in the space around the stem 6. However, with cementless stem implants, there is no need for a centralizer plug, because the walls of the prepared intramedullary canal closely receive, and therefore orient, the stem, as indicated in applicant's Figure 8:



As discussed at ¶0027 of applicant's published application, Figure 8 shows how applicant's claimed compacting broach 10 (not shown in Figure 8) forms a centered cavity 58 in the intramedullary canal 52 for close receipt of side walls 60 of the final rectangular stem implant 26 (side walls 60 and stem 26 are indicated but not shown in Figure 8). In a similar manner, the position of Meyer's broach and implant are determined by the flared proximal fluted portion 34, as indicated in Meyer Figure 6, and there is thus no motivation to add a plurality of fins to the distal end of the Meyer broach for use in centering the broach at the distal end.

It is also important to note that centralizer plugs of the type described in Mackwood Ling are not used to prepare an intramedullary canal for receipt of the femoral stem. Instead, centralizer plugs are used during the step of cementing the final femoral stem implant into a previously prepared canal. As noted above, the centralizer plug serves both to plug the previously prepared canal for receipt of cement, and also to center the stem during the step of curing cement around the stem. Mackwood Ling provides no discussion of the preparation of femoral canals, and instead assumes the existence of a properly prepared canal. The failure of Mackwood Ling to discuss intramedullary canal preparation, much less suggest the use of a centralizer plug during canal preparation, further obviates any suggestion to combine in the manner of the claimed invention.

The record is clear that applicant identified the problem addressed by the present invention, and provided the claimed solution. In applicant's background section, applicant stated:

In the Deyerle patents, the cutting or working sections of the rasps terminate at flat distal end surfaces which lead the rasps into the bone. The distal end configurations of prior rasps and broaches fail to provide any structure for centering the rasps and broaches in the intramedullary canals of the bones prior to the cutting teeth engaging cortical bone. As such, prior rasps and broaches may be introduced into the intramedullary canal off-center, such that the cutting teeth of the rasps and broaches do not evenly engage cortical bone as the rasps and broaches are advanced into the canals.

(¶0005 of applicant's published application). Although Meyer has been substituted in place of the Deyerle reference in the present office action, applicant's observations concerning Deyerle remain directly applicable. Applicant's observations make clear that it was applicant who identified the shortcoming of prior art instruments such as Deyerle and Meyer, and then provided the solution. Meyer, like Deyerle, fails to identify the problem or suggest its solution. In the absence of some teaching, suggestion or motivation to combine the cited references, it is respectfully suggested the obviousness rejection is based on hindsight reconstruction, with applicant's disclosure being used as a blue print to construct the claimed invention.

A *prima facie* showing of obviousness also requires a reasonable expectation of success. As noted in applicant's response to the previous office action, it remains unclear to applicant how putting a centralizer plug of the type described in Mackwood Ling on a broaching instrument such as Meyer would achieve the objective of the present invention. References are not properly combinable if their intended function is destroyed. See e.g. *In re Gordon*, 733 F.2d

900, 221 USPQ 1125 (Fed. Cir. 1984). As indicated in Mackwood Ling Figure 3 above, the Mackwood Ling centralizer plug has an annular opening that is designed to receive a cemented stem having an annular cross-section. It seems clear that a centralizer plug configured to fit on a stem could not be used in a broaching procedure. Mackwood Ling's centralizer plug would have to be significantly modified in order to achieve applicant's claimed structure, and the intended function of Mackwood Ling's centralizer plug would be destroyed. Further, applicant's disclosure provides the sole suggestion or motivation for making the requisite changes to Mackwood Ling.

A *prima facie* showing of obviousness also requires that the prior art references teach or suggest all of the claim elements. The cited references fail to teach or suggest various aspects of the claimed invention. For example, with regard to Claim 3, applicant disagrees with the Examiner's interpretation of Meyer as showing a compacting broach matching "a prosthetic component of rectangular cross section." As far as applicant can determine, Meyer does not show or discuss a prosthetic component having a rectangular configuration, much less a compacting broach matching such a rectangular configuration. Either applicant does not understand the Examiner's reasoning, or the Examiner is disregarding applicant's specification, which should serve as the guide for interpreting the meaning of the claim phrase "a prosthetic component of rectangular cross section."

New claims 21-23 further specify that the cutting teeth along the corner edges extend continuously along each corner edge from a proximal end of the fins to adjacent the rearward end, as shown in applicant's drawings and discussed at ¶0021 of applicant's published application. The claimed configuration is not disclosed in the cited references.

New claims 24-27 further specify that the plurality of fins are fixedly attached to the elongate body of the compactor instrument, such as integrally, as shown in applicant's drawings and discussed at ¶0021 of applicant's published application. The claimed configuration further distinguishes from Mackwood Ling, since Mackwood Ling's centralizer plug merely slips over the distal end of the final implant.

For all of the foregoing reasons, applicant respectfully suggests that a *prima facie* showing of obviousness has not been established.

Conclusion

For the foregoing reasons, it is respectfully suggested that the claims are now in condition for allowance.

It is believed that this response has been filed within the applicable time period for responding and that no extension of time is therefore required, but if an extension is required, applicant hereby requests an appropriate extension of time. It is further believed that no fees are due, but if any fees or credits are due, the Commissioner is authorized to charge or deposit them to Deposit Account No. 502795.

Respectfully submitted,

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